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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,687

10/16/2003

Annapurna Karicherla

A03P1071

2607

36802 7590 03/29/2007
PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/688,687

Applicant(s)

KARICHERLA ET AL.

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-18 and 20-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-18 and 20-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/12/2007 has been entered.

Notice of Amendment

2. In response to the amendment filed on 01/12/2007, amended claim(s) 13, 16, 22, 24, 26, 31-33, and 35, canceled claim(s) 14 and 19, and new claim(s) 39-47 is/are acknowledged. The current rejections of the claim(s) 13, 15-18, 20-28 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Objections

3. Claim 16 is objected to because of the following informalities: the positive recitation of "the pressure sensor pressure" appears to be a typographical error and Applicant may have intended the positive recitation of "the pressure sensor". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the structural relationship between the insulating substrate, the pressure sensor, the layer of insulating material encapsulating the sensor and insulating substrate, and the thin film hermetic material. The Examiner notes the thin film of hermetic material as-claimed is disposed over the insulating material and thus is not contacting the second outer surface of the pressure sensor as positively recited.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 13, 15-18, 20-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (US 5,570,926) in view of Wise et al (US 5,113,868).

10. For claims 13, 22-23, and 31-32, Schulman et al discloses an hermetically sealed implantable sensor for a cardiac pacemaker, comprising:

- an insulating substrate (100) defining an electrical feedthrough region (column 6 lines 16-21 and column 8 line 28 – column 10 line 10);
- a sensor (50) (column 6 lines 21-24) having a first outer surface in contact with said substrate having electrical connectivity with an implantable lead and a second outer surface opposing said first outer surface;
- an electrical conductor (32,113) disposed within said feedthrough region;
- a bond wire (35,105) connecting said conductor to said sensor and disposed within an insulator and/or insulative deposit (column 5 lines 20-27 and column 8 line 28 – column 10 line 10);
- electronic circuitry (45) capable of generating electrical pulses as a pulse generator;
- an implantable lead (96) connected to said conductor and configured for connection to an implantable medical device (column 6 lines 21-24) having electrical connectivity with said pulse generator;
- a layer of insulating material (22,100) (column 3 line 60 – column 4 line 2) encapsulating the sensor and substrate, wherein an inner surface of said film

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contacts the outer surfaces of said sensor and substrate forming a voidless encapsulation (column 1 lines 16-34 and column 8 line 28 – column 10 line 10)

- a thin film of hermetic material (26,110,120) (column 3 line 60 – column 4 line 2) encapsulating the layer of insulating material or the sensor and substrate, wherein an inner surface of said film contacts the outer surfaces of said insulating material or said sensor and substrate forming a voidless encapsulation (column 1 lines 16-34 and column 8 line 28 – column 10 line 10).

11. For claims 15, 25, and 34, Schulman et al discloses a substrate composed of glass (column 3 lines 54-60).

12. For claims 16, 26, and 35, Schulman et al discloses a temperature sensor (column 6 lines 21-24).

13. For claims 17, 27, and 36, Schulman et al discloses a hermetically sealing material comprised of platinum (column 1 lines 35-47).

14. For claims 18, 28, 29, and 37, Schulman et al discloses using an insulating layer thickness of 0.25 mil (column 6 lines 38-39) which equals 0.00635 mm and is thus within the ranges of 10 nm to 0.1 mm and 5.0 nm to 0.5 mm.

15. For claim 20, Schulman et al discloses a conductive pad (36) of material connecting said lead and said electrical conductor.

16. For claims 21, 30, and 38, Schulman et al discloses implanting the hermetically sealed circuitry connected to the lead to pace and sense the heart (column 1 lines 34-53 and column 2 lines 1-19).

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17. Schulman et al discloses the claimed invention except for explicitly disclosing the sensor is a pressure sensor comprising a diaphragm or capacitive type pressure sensor, the sensor is an integrated temperature and pressure sensor, the outer surface of the thin film of hermetic material is exposed to the body, and the thin film of hermetic material deflects with the pressure sensor in response to pressure changes in the body. Wise et al teaches a pressure sensor (30) mounted on an insulator (32) and comprising a capacitive type pressure sensor with a diaphragm (column 3 lines 20-39), the sensor is an integrated temperature and pressure sensor (column 10 lines 12-18), the outer surface of the thin film of hermetic material (414) is exposed to the body (column 14 lines 8-26), and the thin film of hermetic material deflects with the pressure sensor in response to pressure changes in the body (column 14 lines 8-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable sensor as taught by Schulman et al, with the implantable sensor as taught by Wise et al for the purpose of increasing the efficacy of medical diagnostic equipment to provide high precision measurements via sensing equipment.

Response to Arguments

18. Applicant's arguments with respect to claims 13, 15-18, and 20-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)

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272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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